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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,587	08/19/2003	Samuel Bogoch	9425/468031	2933

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EXAMINER	
EMCH, GREGORY S	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,587	BOGOCH ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,15 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,15 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 15, 24 and 25 have been amended and claim 14 has been canceled as requested in the amendment filed on 20 November 2006. Following the amendment, claims 13, 15 and 24-27 are pending in the instant application.

Claims 13, 15 and 24-27 are under examination in the instant office action.

The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants' response and withdrawn.

Double Patenting

The provisional obviousness-type double patenting rejection of claim 13 as being unpatentable over claim 6 of copending Application No. 09/854,568 is maintained for reasons of record and as set forth below.

In the reply filed 20 November 2006, Applicants assert that claim 6 of Application No. 09/854,568 is withdrawn from that application and that upon showing that claim 13 is in condition for allowance and not patentably distinct from issued or allowable claim 6 of the '568 Application, Applicants will file a terminal disclaimer.

Accordingly, until a terminal disclaimer is approved, the rejection is maintained.

The obviousness-type double patenting rejection of claim 13 as being unpatentable over claims 12-14 of U.S. Patent No. 4,298,590 is maintained for reasons of record and as set forth below.

In the reply filed 20 November 2006, Applicants assert that claims 12-14 of the '590 Patent do not contain a limitation directing the claims to SEQ ID NO: 2. Applicants also assert that the patent does not identify or disclose SEQ ID NO: 2 as an epitope on the malignin protein. Applicants argue that the Examiner is incorrect to suggest the antibody of claims 12-14 would specifically recognize a peptide having the amino acid sequence of SEQ ID NO: 2. Applicants also submit their understanding that SEQ ID NO: 2 was not known in the art before the priority date of the above-captioned application. Thus, Applicants assert that without the teachings of the above-captioned application, one of skill in the art would not have known SEQ ID NO: 2 might be both antigenic on its own and an epitope on the malignin protein. As such, Applicants conclude that the '590 patent could not be used to render claim 13 obvious.

Applicants' arguments have been fully considered and are not found persuasive. It is irrelevant that the '590 patent does not teach SEQ ID NO: 2 or that this sequence was antigenic and an epitope on the malignin protein. This is because the malignin protein has the inherent property of comprising the antigenic peptide of SEQ ID NO: 2. Applicants are reminded that a product and its properties are inseparable (see MPEP 2112). In addition, that the '590 patent does not contain claim language that recites SEQ ID NO: 2 is irrelevant since said patent teaches malignin, which meets the claimed limitation of "a peptide having the amino acid sequence of SEQ ID NO: 2" and anti-

malignin, which meets the claimed limitation of an antibody which specifically recognizes "a peptide having the amino acid sequence of SEQ ID NO: 2". Applicants and the Examiner appear to disagree about what is encompassed by the instant claims. Applicants are reminded that claim 13 recites the open language "having," which does not exclude additional unrecited elements (see MPEP 2111.03). Thus, as mentioned above, Applicant's claim 13 reads on an anti-malignin antibody.

Therefore, the rejection is maintained.

The obviousness-type double patenting rejection of claim 24 as being unpatentable over claims 12-14 of U.S. Patent No. 4,298,590 in view of U.S. Patent No. 4,041,146 to Giaever is maintained for reasons of record and as set forth below.

In the reply filed 20 November 2006, Applicants assert that claims 12-14 of the '590 patent do not contain a limitation directing the claims to SEQ ID NO: 1 or SEQ ID NO: 2. Applicants also assert that the patent does not identify or disclose SEQ ID NO: 1 or SEQ ID NO: 2 as antigenic epitopes on the malignin protein. Applicants also submit their understanding that SEQ ID NO: 1 and SEQ ID NO: 2 were not known in the art before the priority date of the above-captioned application. Thus, Applicants assert one of skill in the art would not find it obvious to make an antibody to SEQ ID NO: 1 or SEQ ID NO: 2 and would not find it obvious to use such antibodies to determine the concentration of aglycoprotein 10B antigenic epitopes in the blood of a patient as claimed in claim 24.

Applicants' arguments have been fully considered and are not found persuasive. As set forth above, a product and its properties are inseparable. Since the '590 patent teaches anti-malignin, it inherently teaches antibodies that specifically bind to SEQ ID NO: 1 or SEQ ID NO: 2. Also, it is irrelevant that the skilled artisan did not recognize that the sequences are the antigenic portions of malignin. If the skilled artisan raised a pool of antibodies to the malignin protein, these antibodies would indeed contain antibodies to either of SEQ ID NO: 1 or SEQ ID NO: 2. Further, regarding Applicants' assertion that the skilled artisan would not find it obvious to use such antibodies to determine the concentration of aglycoprotein 10B antigenic epitopes in the blood of a patient is irrelevant. This is because this is an intended use for the claimed kit that is recited by the preamble and thus imparts no patentable weight on the claim (see MPEP 2111.02, section II).

Therefore, the rejection is maintained.

The rejection of claim 13 as being unpatentable over claims 7-11, 20 and 21 of U.S. Patent No. 4,486,538 is maintained for reasons of record and as set forth below.

Similar to the arguments regarding the '590 patent presented above, Applicants submit that claims 7-11, 20 and 21 and the rest of the disclosure of the '538 Patent are not directed to SEQ ID NO: 2. Applicants argue that the Examiner is incorrect to suggest the antibody of claims 7-11, 20 and 21 would specifically recognize a peptide having the amino acid sequence of SEQ ID NO: 2. Applicants also submit their understanding that SEQ ID NO: 2 was not known in the art before the priority date of the

above-captioned application. Thus, Applicants assert that without the teachings of Applicants in the above-captioned application, one of skill in the art would not have known SEQ ID NO: 2 might be both antigenic on its own and an epitope on the malignin protein. As such, Applicants conclude that the '538 patent could not be used to render claim 13 obvious.

Applicants' arguments have been fully considered and are not found persuasive. As set forth above for the '590 patent, it is irrelevant that the '538 patent does not teach SEQ ID NO: 2 or that this sequence was antigenic and an epitope on the malignin protein. This is because the malignin protein has the inherent property of comprising the antigenic peptide of SEQ ID NO: 2. In addition, that the '538 patent does not contain claim language that recites SEQ ID NO: 2 is irrelevant since said patent teaches malignin, which meets the claimed limitation of "a peptide having the amino acid sequence of SEQ ID NO: 2" and anti-malignin antibodies, which meet the claimed limitation of an antibody which specifically recognizes "a peptide having the amino acid sequence of SEQ ID NO: 2". Thus, Applicant's claim 13 reads on an anti-malignin antibody.

The obviousness-type double patenting rejection of claim 24 as being unpatentable over claims 7-11, 20 and 21 of U.S. Patent No. 4,486,538 in view of U.S. Patent No. 4,041,146 to Giaever is maintained for reasons of record and as set forth below.

Similar to the arguments regarding the '590 patent presented above, Applicants assert that claims 7-11, 20 and 21 of the '538 patent do teach antibodies to SEQ ID NO: 1 or SEQ ID NO: 2. Applicants also assert that the patent does not identify or disclose SEQ ID NO: 1 or SEQ ID NO: 2 as an antigenic epitopes on the malignin protein. Applicants also submit their understanding that SEQ ID NO: 1 and SEQ ID NO: 2 were not known in the art before the priority date of the above-captioned application. Thus, Applicants assert one of skill in the art would not find it obvious to make an antibody to SEQ ID NO: 1 or SEQ ID NO: 2 and would not find it obvious to use such antibodies to determine the concentration of aglycoprotein 10B antigenic epitopes in the blood of a patient as claimed in claim 24.

Applicants' arguments have been fully considered and are not found persuasive. As set forth above, a product and its properties are inseparable. Since the '538 patent teaches anti-malignin, it inherently teaches antibodies that specifically bind to SEQ ID NO: 1 or SEQ ID NO: 2. It is irrelevant that the skilled artisan did not recognize that the sequences are the antigenic portions of malignin. If the skilled artisan raised a pool of antibodies to the malignin protein, the pool would indeed contain antibodies to either of SEQ ID NO: 1 or SEQ ID NO: 2. Further, regarding Applicants' assertion that the skilled artisan would not find it obvious to use such antibodies to determine the concentration of aglycoprotein 10B antigenic epitopes in the blood of a patient is irrelevant. This is because this is an intended use for the claimed kit that is recited by the preamble and thus imparts no patentable weight on the claim.

Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

The rejection of claims 13, 15 and 27 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,486,538 to Bogoch is maintained for reasons of record and as set forth below.

In the reply filed 20 November 2006, Applicants assert that they are aware of no teaching or suggestion in the '538 patent of anti-malignin antibodies that bind to SEQ ID NO: 2, as in claim 13, or of a therapeutic composition comprising SEQ ID NO: 1 or SEQ ID NO: 2, as in claim 15. Applicants again submit their understanding that SEQ ID NO: 1 and SEQ ID NO: 2 were not known in the art before the priority date of the above-captioned application. Applicants assert that one of skill in the art could never have guessed that SEQ ID NO: 1 or SEQ ID NO: 2 were epitopes of malignin based on the disclosure of the '538 patent. Applicants argue that the Examiner misstates the teachings of the '538 patent with the assertion that the patent teaches monoclonal anti-malignin antibodies that bind to "a peptide having the amino acid sequence of SEQ ID NO: 2." Applicants also assert that the patent teaches that malignin is approximately 88 amino acids and that the sequence of the protein is not disclosed. Applicants submit that there is no teaching or suggestion for a researcher to even try to create an antibody to SEQ ID NO: 2. In addition, Applicants argue that Example 6 of the instant application teaches differences between the anti-malignin antibodies, such as those in the '538 patent, and the instant antibodies.

Again, Applicants' arguments have been fully considered and are not found persuasive. As set for the above, a product and its properties are inseparable see MPEP 2112). Thus, that the '538 patent does not explicitly recite SEQ ID NO: 2 is irrelevant since said patent teaches malignin, which meets the claimed limitation of "a peptide having the amino acid sequence of SEQ ID NO: 2" and anti-malignin, which meets the claimed limitation of an antibody which specifically recognizes "a peptide having the amino acid sequence of SEQ ID NO: 2". It is also irrelevant that the '538 patent does not disclose the full-length sequence of malignin and that the patent teaches that the sequence is approximately 88 amino acids. That the inventors of the '538 patent had not yet appreciated the sequence of malignin is immaterial, and thus the sequence of malignin is inherently taught by the '538 patent.

It is again noted that Applicants and the Examiner appear to disagree about what is encompassed by the instant claims. Applicants are reminded that claim 13 recites the open language "having," and claim 15 recites the open language "comprising" both of which do not exclude additional unrecited elements. Thus, as mentioned above, Applicant's claim 13 reads on an anti-malignin antibody, while claim 15 reads on a therapeutic composition comprising malignin.

Further, since the '538 patent teaches anti-malignin, it inherently teaches antibodies that specifically bind to SEQ ID NO: 1 or SEQ ID NO: 2. It is irrelevant that the skilled artisan did not recognize that these sequences are the antigenic portions of malignin. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) [Emphasis added]. Furthermore, if the skilled artisan raised a pool of antibodies to the malignin protein, the pool would indeed contain antibodies to SEQ ID NO: 1 and SEQ ID NO: 2, as these are the antigenic portions of the full-length protein. Also, regarding Applicants' assertion that the skilled artisan would not know that the sequences would be useful as therapeutic agents to increase antimalignin antibodies is immaterial. This is because this is an intended use recited by the preamble and thus imparts no patentable weight on claim 15.

In addition, the instant Example 6 reinforces the Examiner's argument that antibodies raised against malignin (as disclosed in the '538 patent) and those raised against SEQ ID NOs: 1 and 2 are indeed the same. Starting at p.22 of the instant specification, it is taught that SEQ ID NO: 2 was injected subcutaneously into rabbits. Following subsequent booster injections, the animals were bled to determine "antimalignin antibody concentration," in which the antibody was immunoadsorbed against intact immobilized "aglycoprotein 10B (malignin)." The results show that both the "fast-binding antibody" (F-TAG) and the "slow-binding antibody" (S-TAG) increase significantly over baseline levels (pre-injection levels). On pp.23-24, it is taught, "This increase in F-TAG before the increase in S-TAG is the same as that seen *in vitro* when isolated lymphocytes in tissue culture are induced by intact Aglyco 10B to produce antimalignin antibody (Cancer Detection and Prevention 12:313-320, 1988). The repetition of this phenomenon with synthetic peptide epitopes injected into rabbits is

further confirmation of the fact that the synthetic peptides reproduce exactly the production and release into serum of antimalignin antibody" [Emphasis added].

Furthermore, on p.24, it is taught that as in the 1988 study referred to above, the antimalignin antibody to Aglyco 10B is of the IgM type, with little or none being of the IgG type. In the present study where the synthetic antigen of SEQ ID NO: 2 was injected, "a separate determination was made of the antibody produced to determine whether IgG was more prevalent." Here, "the post- injection levels of IgG did not differ from the pre-injection levels." The results with SEQ ID NO: 1 are disclosed on pp.25-26. Here, the F-TAG and S-TAG were again analyzed and "the post-injection levels of IgG rose to a very high level." Thus, it is taught that the IgG type of antibody is a "novel antibody."

In view of Example 6, it is noted that although the 1988 study teaches a majority of antibody being of the IgM type (as taught by the specification), the specification still teaches that "little" was of the IgG type. That SEQ ID NO: 1 causes production of more IgG anti-malignin antibody than the prior art does not mean that said antibody is novel. Further, the underlined portions of the specification presented above further support the view that the anti-malignin of the prior art (the 1988 study as well as the '538 patent) and that of the instant application are the same. Regardless, the '538 patent teaches anti-malignin IgG antibodies (e.g., col.32, lines 8-30). Additionally, assuming *arguendo* that the IgG anti-malignin antibody of Example 6 was novel, Applicants are reminded that although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Also in the reply filed 20 November 2006, Applicants assert that the '538 patent provides no teaching or suggestion concerning an isolated nucleic acid encoding a peptide comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2, as in the instant claim 27.

This is not persuasive because "comprising" is open language, which does not exclude additional unrecited elements. Thus, as stated previously, the instant claim 27 encompasses an isolated nucleic acid encoding malignin.

Therefore, claims 13, 15 and 27 are anticipated by U.S. Patent No. 4,486,538 to Bogoch.

The rejection of claim 15 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,298,590 to Bogoch is maintained for reasons of record and as set forth below.

In the reply field 20 November 2006, Applicants assert that the '590 patent does not teach or suggest the claimed composition since it does not teach or suggest SEQ ID NO: 1 or SEQ ID NO: 2 or a therapeutic composition for increasing antimalignin concentration.

As set forth above, the '590 patent teaches a therapeutic composition "comprising" the peptide of SEQ ID NO: 1 or the peptide of SEQ ID NO: 2, since it

teaches malignin. Also, the intended use is not given patentable weight. Thus, the rejection is maintained.

Claim Rejections - 35 USC § 103

The rejection of claims 13, 15 and 24-27 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,486,538 to Bogoch in view of U.S. Patent No. 4,041,146 to Giaever is maintained for reasons of record and as set forth below.

In the reply filed 20 November 2006, Applicants again rely on arguments that since SEQ ID NO: 1 or 2 were not known and that the skilled artisan could not have guessed that these sequences were the epitopes of malignin. Further, regarding the kit of claims 24-26, Applicants submit that the skilled artisan could never have arrived at the use of SEQ ID NO: 1 or SEQ ID NO: 2 in a kit for detecting anti-malignin antibody or the use of antibodies to SEQ ID NO: 1 or SEQ ID NO: 2.

Again, Applicants' arguments have been fully considered and are not found persuasive. As referred to above, the knowledge of the specific epitopes of malignin is not required, since malignin and anti-malignin (as disclosed by the prior art of record) meet the claimed limitations of amino acid molecules "comprising" or "having" SEQ ID NO: 1 or SEQ ID NO: 2 and antibodies to said molecules. Also, regarding the kits of claims 24-26, the intended uses in the preambles are given no patentable weight.

Thus, the rejection under 35 U.S.C. 103(a) is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 9AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
25 January 2007

ELIZABETH KEMMERER
PRIMARY EXAMINER